**Attorney Docket No. S-2481/CONT**
**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|
| In re Application of: | ) | Group Art Unit: Unknown |
| | ) | |
| YOKOYAMA; HONZAWA; OGAWA | ) | Examiner: Unknown |
| | ) | |
| Serial No. Continuation of parent appln. S.N. 09/778,901 | ) | |
| | ) | |
| Filed: Concurrently herewith | ) | |

For: **PRODUCTION PROCESS FOR POLYMERIC MICELLE CHARGED THEREIN WITH DRUG AND POLYMERIC MICELLE COMPOSITION**

## Appendix A

Please amend the specification as indicated according to 37 C.F.R. §1.121 concerning a manner for making amendments to the specification.

Please add the following new paragraph on page 1 after the title of the invention:

--CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Serial No. 09/778,901, filed on February 08, 2001, which claims foreign priority to JP 2000-32156 filed on February 9, 2000.--

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For: **PRODUCTION PROCESS FOR POLYMERIC MICELLE CHARGED THEREIN WITH DRUG AND POLYMERIC MICELLE COMPOSITION**

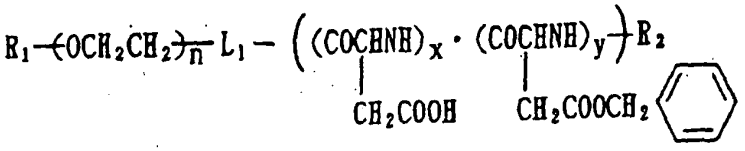
## Appendix B

Please amend the claims as indicated according to the revision to 37 C.F.R. §1.121 concerning a manner for making claim amendments.

1. (Currently amended) A production process for a polymeric micelle charged therein with a water-scarcely soluble drug, comprising the steps of:

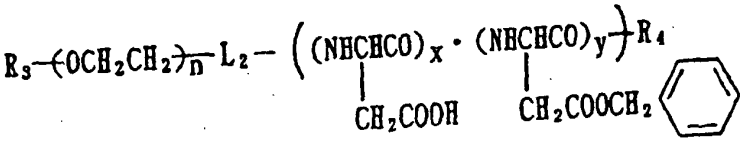
(A) dissolving a water-scarcely soluble drug and a block copolymer having a hydrophilic segment and a hydrophobic segment in a water non-miscible organic solvent to prepare an organic solution,

wherein the block copolymer is represented by the following Formula (I) or (II)



(I)

or



(II)

wherein $R_1$ and $R_3$ represent a hydrogen atom or a lower alkyl group; $R_2$ represents a hydrogen atom, a saturated or unsaturated $C_1$ to $C_{29}$ aliphatic carbonyl group or an arylcarbonyl group; $R_4$ represents a hydroxyl group, a saturated or unsaturated $C_1$ to $C_{30}$ aliphatic oxy group or an aryl-lower alkyloxy group; $L_1$ represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a $C_1$ to $C_4$ alkylene group); $L_2$ represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a $C_1$ to $C_4$ alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 7 : 3 to 1 : 3,

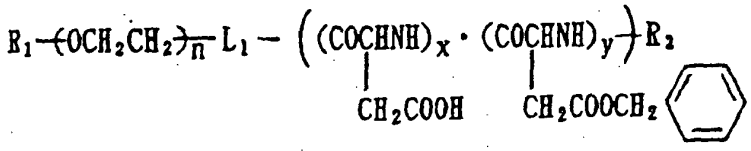
(B) mixing the resulting organic solution with an aqueous medium to form an oil-in-water (O/W) type emulsion,

(C) vaporizing and removing the above organic solvent from the resulting emulsion to form a polymeric micelle solution charged therein with the above drug, and

(D) subjecting the resulting polymeric micelle solution, if necessary, to supersonic treatment and ultrafiltraton treatment.

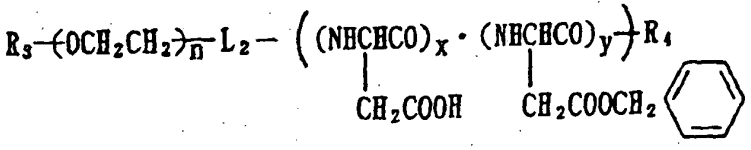
Claims 2-9 (Cancelled)

10. (Currently amended) A composition comprising a polymeric micelle originating in a block copolymer charged therein with a drug, wherein the drug is a water-scarcely soluble drug; the block copolymer is represented by the following Formula (I) or (II):



(I)

or



(II)

† wherein $R_1$ and $R_3$ each represent a hydrogen atom or a lower alkyl group; $R_2$ represents a hydrogen atom, a saturated or unsaturated $C_1$ to $C_{29}$ aliphatic carbonyl group or an arylcarbonyl group; $R_4$ represents a hydroxyl group, a saturated or unsaturated $C_1$ to $C_{30}$ aliphatic oxy group or an aryl-lower alkyloxy group; $L_1$ represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a $C_1$ to $C_4$ alkylene group); $L_2$ represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a $C_1$ to $C_4$ alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 7 : 3 to 1 : 3; and x and y each are present at random†; a micelle solution prepared by dissolving or dispersing the above micelle in water can stably be maintained in a drug concentration of at least 3 mg per ml of the solution.

11. (Original) The composition as described in claim 10, wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and topotecan.

Claims 12 (Cancelled)

13. (New) The production process as described in claim 1, wherein the drug and the block copolymer are used in a weight ratio of 1:10 to 3:10.

14. (New) The production process as described in claim 1 wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and toptecan.

15. (New) The composition as described in claim 10, wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and topotecan, and wherein said micelle solution can stably be maintained in a drug concentration of at least 6 mg per ml of the solution.

16. (New) The composition as described in claim 10, wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and topotecan, and wherein said micelle solution can stably be maintained in a drug concentration of at least 10 mg per ml of the solution.

17. (New) The composition as described in claim 10, wherein the drug is paclitaxel and an analogue thereof, and wherein said micelle solution can stably be maintained in a drug concentration of at least 6 mg per ml of the solution.

18. (New) The composition as described in claim 10, wherein the drug is paclitaxel and an analogue thereof, and wherein said micelle solution can stably be maintained in a drug concentration of at least 10 mg per ml of the solution.